UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456
	)	CIVIL ACTION: 01-CV-12257-PBS
	)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.*, No. 06-CV-11337-PBS	)	Magistrate Judge Marianne B. Bowler

ABBOTT LABORATORIES, INC.'S MEMORANDUM IN SUPPORT OF MOTION TO DISMISS FOR LACK OF SUBJECT-MATTER JURISDICTION UNDER THE PUBLIC DISCLOSURE BAR

Dated: June 26, 2009

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Discovery has confirmed that Ven-A-Care has no first-hand, independent knowledge of its allegations against Abbott, and thus it is not a proper relator in this matter. Ven-A-Care has failed to point to any facts showing that it had direct knowledge that Abbott sold the Subject Drugs with an inflated "spread" and marketed that spread, or that Ven-A-Care provided evidence of this conduct to the Government before filing suit. To the contrary, Ven-A-Care's officers candidly admit that they learned of Abbott's alleged "fraud" by researching third-party group purchasing organization ("GPO") catalogs and other publications that were equally available to thousands of other pharmacies.

The False Claims Act does not permit this Court to exercise jurisdiction over a *qui tam* action under these circumstances – namely, where the allegations in the complaint were publicly disclosed before the complaint was filed and the relator cannot show direct and independent knowledge of the allegations. As this Court is aware, the media and government reported on AWP inflation and "marketing the spread" long before relator Ven-A-Care first made such allegations in this *qui tam* action. Those disclosures explicitly and implicitly discussed Abbott and the four Subject Drugs at issue in this case. Because Ven-A-Care had no direct knowledge of the allegations against Abbott, the Court lacks jurisdiction unless and until Ven-A-Care is dismissed from the case. *See Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 477 (2007).

ARGUMENT

It is well recognized that *qui tam* actions under the FCA are "susceptible to abuse . . . by 'parasitic' relators who bring FCA damages claims based on information within the public domain or that the relator did not otherwise discover." *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 727 (1st Cir. 2007). Such opportunistic plaintiffs are weeded out by the FCA's public disclosure bar, which provides that the district courts have no jurisdiction over suits that are based on "allegations or transactions" that have been "public[ly] disclos[ed]. . . in a criminal,

civil, or administrative hearing, in a congressional, administrative, or [GAO] report, hearing, audit, or investigation, or from the news media," unless the relator "is an original source of the information." *Id.* at 728 (quoting 31 U.S.C. § 3730(e)(4)(A)). The fact that the Government elects to intervene in such an action does not cure the jurisdictional defect; the improper relator must still be dismissed from the action. *Rockwell*, 549 U.S. at 477 ("reject[ing]" argument that "inquiry into [the relator's] original-source status . . . was unnecessary because the Government had intervened" and requiring dismissal of relator to cure jurisdictional defect).

Therefore, as the First Circuit has held, the "threshold question in a False Claims Act case is whether the statute bars jurisdiction." *Rost*, 507 F.3d at 727. The "Relator carries the burden of proving jurisdiction." *In re Pharm. Indus. AWP Litig.*, 538 F. Supp. 2d 367, 375 (D. Mass. 2008). Whether the relator has met its burden depends on "several inquiries":

> (1) whether there has been public disclosure of the allegations or transactions in the relator's complaint; (2) if so, whether the public disclosure occurred in the manner specified in the statute; (3) if so, whether the relator's suit is 'based upon' those publicly disclosed allegations or transactions; and (4) if the answers to these questions are in the affirmative, whether the relator falls within the 'original source' exception as defined in § 3730(e)(4)(B).

Rost, 507 F.3d at 728. Courts "look to the amended complaint to determine jurisdiction" to avoid a "relator . . . plead[ing] a trivial theory of fraud" and "later amend[ing] the complaint to include theories copied from the public domain or from materials in the Government's possession." *Rockwell*, 549 U.S. at 473, 474.

Although courts often analyze first whether issues were publicly disclosed, the record here unmistakably demonstrates that Ven-A-Care had no direct knowledge of any of the allegations of the 2007 First Amended Complaint, and thus is not an original source. Accordingly, we address that argument first. Once it is established that Ven-A-Care is not an original source of the allegations in the amended complaint, any allegations that the Court

determines were publicly disclosed are jurisdictionally barred, and can be cured only if, as in *Rockwell*, the relator is dismissed from this case.

I. RELATOR VEN-A-CARE IS NOT AN ORIGINAL SOURCE OF THE ALLEGATIONS IN THE FIRST AMENDED COMPLAINT.

To be an "original source," a relator must have "direct and independent knowledge" of the "information upon which the relators' allegations are based." *Rockwell*, 549 U.S. at 470-71. This "definition [is] conjunctive, requiring the relator to have both 'direct' and 'independent' knowledge." *In re Pharm. Indus. AWP Litig*., 538 F. Supp. 2d at 379. The relator must establish original source claim by claim; "[s]ection 3730(e)(4) does not permit jurisdiction in gross just because a relator is an original source with respect to some claim."[1] *Rockwell*, 549 U.S. at 476.

As this Court has held, "[f]or a relator's knowledge to be direct, it must be marked by the absence of an intervening agency, instrumentality, or influence. In other words, direct knowledge is mediated only by the plaintiff's own labor." *United States ex rel. O'Keeffe v. Sverdup Corp.*, 131 F. Supp. 2d. 87, 95 (D. Mass. 2001) (Saris, J.) (internal citations and quotation marks omitted); *see also United States ex rel. Findley v. FPC-Boron Employees' Club*, 105 F.3d 675, 690 (D.C. Cir. 1997) ("In order to be 'direct,' the information must be firsthand knowledge."); *United States ex rel. Fine v. Advanced Scis., Inc.*, 99 F.3d 1000, 1006-07 (10th Cir. 1996) ("[D]irect knowledge is knowledge gained by the relator's own efforts and not acquired from the labors of others."). "[T]o be independent, the relator's knowledge must not be derivative of the information of others," *Advanced Scis.*, 99 F.3d at 1007, and must be independent of public disclosures. Thus, in this MDL, the Court has found that a salesman whose employer "instructed him to market the spread created by rebate checks" had direct and independent knowledge of that

[1] Ven-A-Care should be required to prove that it is an original source on an NDC-by-NDC basis. Abbott recognizes that this Court has rejected such an approach in the past, in favor of a drug-by-drug approach. *See In re Pharm. Industry AWP Litig.*, 538 F. Supp. 2d at 399. As shown below, however, Ven-A-Care cannot even establish that it is an original source for each particular Subject Drug.

allegation. *In re Pharm. Indus. AWP Litig.*, 538 F. Supp. 2d 367, 384 (D. Mass. 2008).

By contrast, "any information supporting a FCA action that Relator gained through his analysis of existing data is [] insufficiently direct to make him an original source." *O'Keeffe*, 131 F. Supp. 2d at 96; *see also, e.g., United States ex rel. Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1159 (2d Cir. 1993) ("collateral research and investigations . . . [do] not establish 'direct and independent knowledge of the information on which the allegations are based within the meaning of § 3730(e)(4)(B)'"); *United States ex rel. Alcohol Found., Inc. v. Kalmanovitz Charitable Found., Inc.*, 186 F. Supp. 2d 458, 463-64 (S.D.N.Y.) (rejecting argument that relator was original source based on "the 'perspective' [its] members obtained by spending hundreds of hours compiling facts into a 'mosaic'"), *aff'd*, 53 F. App'x 153 (2d Cir. 2002). Even when a "Relator argues that his particular interdisciplinary expertise and background allow him to understand the significance of publicly disclosed information, that is not enough to qualify him as an original source." *O'Keeffe*, 131 F. Supp. 2d at 96 (citing *Kreindler*, 985 F.2d at 1159).

Even if it has direct and independent knowledge, a party is not an original source unless it "voluntarily provides the information to the Government before filing an action." 31 U.S.C. § 3730(e)(4)(B). Here, Plaintiffs have refused to provide the pre-complaint disclosure Ven-A-Care submitted to the DOJ, and Abbott cannot assess whether Ven-A-Care satisfied this obligation. As Ven-A-Care retains the burden of showing jurisdiction, however, it should either (1) waive any privilege asserted with respect to its disclosure and show that it, in fact, "voluntarily provided" original source information to the Government prior to filing; or (2) maintain the privilege but forfeit its claim to original source status.

A. Ven-A-Care, As A Corporation, Cannot Be An Original Source.

As a corporation, Ven-A-Care can be a relator, but not an original source under the plain text of the FCA. The statute provides that a "a person may bring a civil action" under the FCA,

31 U.S.C. § 3730(b)(1); that "a person shall have the right to continue as a party to the action" if the Government does not intervene, *id.* § 3730(c)(1); that "[i]f the Government proceeds with an action brought by a person under subsection (b), such person shall" receive part of the recovery, *id.* § 3730(d), and that there is no jurisdiction over publicly-disclosed allegations unless "the person bringing the action is an original source," *id.* § 3730(e)(4)(A) (all emphasis added). Although these provisions use the term "person," the next subparagraph makes clear that "'original source' means an individual who has direct and independent knowledge." *Id.* § 3730(e)(4)(B) (emphasis added).

The term "person" under the FCA is a standard statutorily-defined term which, "include[s] corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals." 1 U.S.C. § 1; *see also, e.g., Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 782 (2000) (looking to 1 U.S.C. § 1 in defining scope of term "person" under FCA). A corporation is thus a "person." As the statutory definition of "person" indicates, however, an "individual" is *not* a "corporation," but rather is something distinct from a "corporation." *See* 1 U.S.C. § 1. Indeed, in *In re Spookyworld, Inc.*, 346 F.3d 1, 7 (1st Cir. 2003), the First Circuit found that similar language in a statute that likewise "define[d] 'person' to include 'individuals, partnerships, and corporations," showed that "the term [individual] was not meant to include corporations."[2]

Congress's use of the narrower term "individual" in the original source provision is significant, as "when Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Allison Engine Co. v. United States ex rel.*

[2] In *Lee v. ABC Carpet & Home*, 236 F.R.D. 193, 198 (S.D.N.Y. 2006), Judge Batts likewise held that where the statutory term "person" was defined as "an individual, partnership, association, [or] corporation," the term "'individual' . . . does not include corporations."

Sanders, 128 S.Ct. 2123, 2129-2130 (2008). Thus, "'[t]he use of different terms within related statutes generally implies that different meanings were intended.'" *United States v. Bean*, 537 U.S. 71, 76 n.4 (2002) (internal citation omitted); *see also, e.g., Soliman v. Gonzales*, 419 F.3d 276, 283 (4th Cir. 2005) ("Where Congress has utilized distinct terms within the same statute, the applicable canons of statutory construction require that we endeavor to give different meanings to those different terms"); *DIRECTV, Inc. v. Brown*, 371 F.3d 814, 818 (11th Cir. 2004) (same).

In fact, when Congress "goes out of its way to avoid [a] standard term" in a specific section of a statute, having used it elsewhere, the presumption "that Congress acts intentionally and purposely when it includes particular language in one section of a statute but omits it in another . . . *is even stronger*." *BFP v. Resolution Trust Corp.*, 511 U.S. 531, 537 (1994) (rejecting argument that term "reasonably equivalent value" meant "fair market value" where Congress had used term "fair market value" elsewhere in statutory scheme) (emphasis added). That presumption "becomes a certitude" when the "standard" terminology would be strained or inconsistent if used in the place of the differing language drafted by Congress. *See id.*

Congress's decision to avoid the standard term "person" in 31 U.S.C. § 3730(e)(4)(B)—a broad term encompassing both corporations and individuals—and instead to require an original source to be an "individual," must be presumed as meaningful and deliberate, particularly given its repeated use of the more-inclusive term "person" elsewhere in the very same section and paragraph. *See* 1 John T. Boese, *Civil False Claims and* Qui Tam *Actions*, § 4.02[D], at 4-108.8 (3d ed. 2009-1 supp.) (noting that an "organization may be absolutely barred from bringing suits in cases of public disclosure," as "the original source rule does not refer to the relator as the 'person' . . . but as the 'individual.'"). Indeed, such a requirement is logical given that an

original source must have "direct," and not second-hand, knowledge of the information upon which his or her claims are based. *See O'Keeffe*, 131 F. Supp. 2d at 95. It is axiomatic that "[a] corporation acts only through its agents," *Sriberg v. Raymond*, 544 F.2d 15, 16 (1st Cir. 1976), and therefore "can acquire [] knowledge only through its agents," *City State Bank in Wellington v. U.S. Fid. & Guar. Co.*, 778 F.2d 1103, 1109 (5th Cir. 1985) (internal punctuation omitted). All corporate knowledge is second-hand.

Likewise, defining an "original source" as an "individual" is consistent with the "paradigm of the inside whistleblower." *O'Keeffe*, 131 F. Supp. 2d at 93. The legislative history of the 1986 amendments repeatedly references the idea of an individual employee providing insider information about her employer's false claims. *See, e.g.*, S. Rep. No. 99-345, at 34 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5299 ("few individuals will expose fraud if they fear their disclosures will lead to harassment, demotion, loss of employment, or any other form of retaliation"). By contrast, the legislative history does not discuss corporate relators, let alone anything that could overcome the presumption that the use of the term "individual" rather than "person" was deliberate. Given that language, Ven-A-Care is not, by definition, an original source of the allegations set forth in the Government's complaint.

B. Even If It Is An "Individual," Ven-A-Care Is Not An Original Source.

Even if Ven-A-Care were an "individual" for purposes of § 3730(e)(4)(B), it still would be unable show that it is an original source of the claims in the current operative complaint, the 2007 First Amended Complaint. Ven-A-Care admits that it has no direct evidence of Abbott's alleged "marketing the spread" or "AWP inflation" with respect to the Subject Drugs. Rather, its claims are based wholly on collateral research and second-hand information.

1. Ven-A-Care Has No Direct And Independent Knowledge That Abbott Marketed The Spread For The Subject Drugs.

The 2007 First Amended Complaint alleges that Abbott caused "false and fraudulent claims to be submitted" by "knowingly us[ing] the spread as an unlawful inducement in violation of the federal anti-kickback statute," and made false statements to cause such claims to be paid. (Ex. A ¶¶ 140, 143.) The factual basis for this allegation is that "[i]nternal memoranda from senior Abbott sales staff reveal that Abbott actively knew about and marketed the large spreads on several of its drugs, including Vancomycin," and that, when customers complained about small spreads, Abbott "deliberated" on how to "reestablish the inducement that had come to be expected by its Customers." (Ex. A ¶¶ 76, 79.) Abbott allegedly "engaged in similar conduct" with respect to sterile water, sodium chloride, and dextrose. (*Id.* ¶¶ 91-102.) Ven-A-Care has never alleged, let alone offered proof, that it had access to internal Abbott memoranda or deliberations prior to filing its *qui tam*, and thus it cannot be an original source of these claims.

Moreover, Ven-A-Care does not appear to have direct knowledge of *any* kind that Abbott marketed the spread with respect to the Subject Drugs. Ven-A-Care's 1997 Second Amended Complaint made allegations about an Abbott sales representative marketing the spread with respect to acyclovir, a drug that is no longer in the case;[3] by contrast, it made no specific allegations that Abbott ever marketed the spread as to the Subject Drugs. (Ex. B ¶ 48). Indeed, apart from a May 1997 conversation about acyclovir between Abbott representative Dennis Walker and Ven-A-Care's then president, Zach Bentley (an exchange that was engineered by Bentley (Dkt. No. 4720 at 2-5)), Ven-A-Care's witnesses could not testify that any Abbott representative had ever "attempt[ed] to sell its product based upon the difference between reimbursement amounts and acquisition cost" for any product, let alone with respect to the

[3] The Court allowed the Government to plead acyclovir claims in its First Amended Complaint, but ultimately held that all acyclovir claims were untimely. (*See* Dkt. 5143, at 12-13; Electronic Order of April 9, 2008.)

Subject Drugs. (*See, e.g.*, Ex. C at 409:19-410:3; Ex. D at 94:12-21). Nor could Ven-A-Care point to any advertisements, marketing material, or other documentation that it received showing Abbott marketing the spread on any drug. (Ex. C at 92:6-93:3; Ex. E at 523:4-524:16.)[4]

2. Ven-A-Care's Claimed Knowledge Of Alleged Inflation Of AWP By Abbott Is Based On Second-Hand Research.

Ven-A-Care's June 1995 complaint did not allege that Abbott "marketed the spread" or encouraged providers to submit false claims. (*See* Ex. F ¶¶ 48-51, 84-105.) Rather, it charged Abbott with the "reporting of grossly inflated, false and fraudulent cost and price information regarding certain pharmaceutical products" that "[Abbott] knew would be relied upon by" Medicare and Medicaid, causing them to "pay grossly excessive and unreasonable reimbursement." (*Id.* ¶¶ 1, 48). Ven-A-Care cannot establish that it is an original source of this "bare AWP inflation" theory of fraud. Throughout discovery, Ven-A-Care's officers have repeatedly admitted that their claims about Abbott inflating AWPs above acquisition cost were acquired through research and compilation of second-hand published materials. For instance, its 30(b)(6) witness T. Mark Jones testified:

> We did a lot of research [in] the compendia. We started looking at published prices as opposed to prices that we were able to get as an industry insider, you know, having contracts with wholesalers or pharmaceutical manufacturers or GPOs. So we started compiling those.

(Ex. G at 90:6-91:2). But none of the materials, including price lists, came directly from Abbott; he gleaned those prices from "GPO documents [he] received from GPOs." (*Id.* at 140:22-142:4).

Ven-A-Care's other officers testified similarly. Luis Cobo acknowledged that Ven-A-Care merely "compare[d] published prices to price lists available to Ven-A-Care to purchase

[4] To be sure, Ven-A-Care has claimed that proof of inflated AWPs alone is sufficient to show "passive" marketing of the spread. (*See, e.g.*, Ex. C at 406:19-407:2). This Court, however, held otherwise; with respect to "Abbott's multi-source drugs," the Court ruled that "mere publication of a false AWP, without more, does not constitute an offer of remuneration." *In re Pharm. Indus. AWP Litig.*, 491 F. Supp. 2d 12, 19 (D. Mass. 2007). So Ven-A-Care's claim that Abbott *had* a spread is not evidence of *marketing* the spread.

from these GPOs and other sources." (Ex. E at 530:4-531:4) Dr. John Lockwood acknowledged:

> I learned things about Red Book, a pricing compendia, and read what they said about some things. I looked at what I could from First Databank and other pricing compendia. And occasionally we were able to obtain older compendia that sometimes described how prices were set in one way, and more recent compendia that really showed how prices were at least represented perhaps in a different way. So that through reading and understanding about the marketplace I think I developed some understanding of how prices are represented in the marketplace by manufacturers.
>
> Q. And you obtained that understanding through essentially research, correct?
>
> MR. BREEN: Objection to form.
>
> A. Yes, I would say that would be true.

(Ex. D at 109:20-110:15). Dr. Lockwood also confirmed that "other pharmacies that were in the same class of trade as Ven-A-Care had the same pricing available in general that Ven-A-Care had," and that this "knowledge *was not unique to Ven-A-Care* but was probably known by every pharmacy that could buy these drugs, and/or did buy those drugs." (*Id.* at 237:19-22; 243:15-22.)

Tellingly, Ven-A-Care's officers could not identify any specific purchases or transactions with Abbott through which it might have learned of alleged AWP inflation. (*See, e.g.* Ex. C at 369:4-20; 388:19-389:11; Ex. E at 529:4-11.) Nor was Ven-A-Care well-positioned to obtain such evidence; by the mid-1990s, it had largely stopped seeing patients, and it was purchasing drugs mainly to shore up its various *qui tam* lawsuits. Its current president T. Mark Jones admits: "I don't believe Ven-a-Care has purchased every drug in each of the lawsuits." (Ex. C at 382:19-383:8; Ex. D at 196:22-197:22, 376:12-377:1; Ex. H at 282:2-286:3).

Thus, Ven-A-Care is not an original source, and this is not a proper *qui tam*. It is a parasitic action against Abbott, based not on what Ven-A-Care knew, but what Ven-A-Care read.

II. THE ALLEGATIONS OF THE FIRST AMENDED COMPLAINT ARE BASED ON PUBLIC DISCLOSURES

Because Ven-A-Care is not an original source, this Court must examine whether the

allegations of the 2007 First Amended Complaint were publicly disclosed before Ven-A-Care brought its claims. If they were, the Court lacks subject-matter jurisdiction over those claims.

"[A] 'public disclosure' requires that there be some act of disclosure to the public outside of the government." *Rost*, 507 F.3d at 728. This Court has adopted the "widely accepted framework for determining whether a public disclosure of the allegations or transactions has occurred" set forth by the D.C. Circuit. *See In re Pharm. Indus. AWP Litig.*, 538 F. Supp. 2d at 383; *O'Keeffe*, 131 F. Supp. 2d. at 94. That framework uses the shorthand "X + Y = Z," where "X stands for the allegedly false set of facts set forth in the claim at issue," "Y is a proxy for the allegedly true set of facts," and "Z represents the allegation of fraud." *O'Keeffe*, 131 F. Supp. 2d at 94 (citing *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 654 (D.C. Cir. 1994)). When "X [the false set of facts] and Y [the true set of facts] surface publicly, or when Z is broadcast . . . , there is little need for *qui tam* actions, and the claim will be barred unless the relator qualifies as an original source." *Id.*

A public disclosure need not specifically identify all particulars of the alleged fraud. It is sufficient if it "'set[s] the government squarely on the trail of fraud' such that it would not have been difficult for the government to identify [the defendant] as a potential wrongdoer." *In re Pharm. Industry AWP Litig.*, 538 F. Supp. 2d at 383 n.10 (D. Mass. 2008).[5] And while disclosure must occur through the categories enumerated in the statute, *Rost*, 507 F.3d at 728, the "elements of the fraud allegation need not be made public in a single document," *United States v. Catholic Healthcare W.*, 445 F.3d 1147, 1151 (9th Cir. 2006), but rather can come from multiple sources "considered as a whole." *United States ex rel. Reagan v. E. Tex. Med. Ctr.*

[5] Indeed, in another MDL *qui tam* alleging "industry-wide" fraud against scores of defendants, the Tenth Circuit recently held that a report constituted a public disclosure, even as to defendants not specifically named, because it involved an "identified technique" of fraud by a finite group of companies the Government could identify from its records. *In re Nat. Gas Royalties Qui Tam*, 562 F.3d 1032 (10th Cir. 2009) (Ex. I).

Reg'l Healthcare Sys., 384 F.3d 168, 174 n.8 (5th Cir. 2004); *see also Dingle v. Bioport Corp.*, 388 F.3d 209, 214 (6th Cir. 2004) ("The fact that the information comes from different disclosures is irrelevant"). Disclosures may occur in one or more of:

- The "news media," which includes newspapers, magazines, and other publications that "disseminate information to the public in a periodic manner" and "are as generally accessible to any other strangers to the fraud as would be a newspaper article." *Alcohol Found.*, 186 F. Supp. 2d at 463; *see also In re Nat. Gas Royalties Qui Tam Litig.*, 467 F. Supp. 2d 1117, 1155 (D. Wyo. 2006) (disclosure in a trade journal is in the "news media").

- An administrative or congressional "report," *See* 31 U.S.C. § 3730(e)(4)(A), including reports issued by HCFA or HHS's Office of Inspector General. *See, e.g., United States v. Adminastar Fed., Inc.*, 324 F.3d 492, 496 (7th Cir. 2003).

- The course of an "investigation" or "audit," 31 U.S.C. § 3730(e)(4)(A), such as when federal investigators share "documents from [their] investigations" and "information learned in them" with third parties. *Seal 1 v. Seal A*, 255 F.3d 1154, 1161 (9th Cir. 2001); *see also United States ex rel. Gross v. AIDS Res. Alliance-Chi.*, 415 F.3d 601, 606 (7th Cir. 2005) (FDA letter citing regulatory violations was a public disclosure).

Finally, allegations are "'based upon' a public disclosure when the allegations in the relator's complaint are similar to, supported by, or the same as those that have been publicly disclosed regardless of where the relator obtained his information." *In re Pharm. Indus. AWP Litig.*, 538 F. Supp. 2d 367, 377-379 (D. Mass. 2008) (internal citations and quotations omitted).

A. The "Marketing The Spread" Allegations Are Based Upon Disclosures From Both A 1996 *Barron's* Article And A 1987 *Lexington Herald-Leader* Article.

The Government's 2007 First Amended Complaint focuses on a "marketing the spread" theory, alleging that Abbott "deliberate[ly] manipulat[ed] its published prices to induce its Customers to purchase the Drugs" (Ex. A ¶ 70), and that Abbott "manipulated its LPs, AWPs, and WACs to induce its Customers to purchase Abbott's products, including the Drugs, by marketing the huge profits that would result to its customers." (*Id.* ¶ 67; *see also id.* ¶ 36 (alleging that Abbott "actively marketed the government-funded profits or 'spreads' on its drugs")) Ven-A-Care first raised this theory in its August 12, 1997 amended complaint. (Ex. B

¶ 48.)

A year prior to that filing, however, this allegation against Abbott was disclosed by a June 10, 1996 *Barron's* article entitled "Hooked on Drugs." (Ex. J.) The article's premise is that "drug providers actually pay wholesale prices that are 60-90% below the so-called average wholesale price, or AWP, used in reimbursement claims." (*Id.* at 1.) Abbott is identified by name as maintaining a 277% spread on vancomycin. (*Id.* at 5.) The article adds that "pricing unreality is even worse for intravenous nutritionals and solutions, a category dominated by Abbott Laboratories and Baxter International. Catalog wholesale prices for these items are, on average, 80%-93% below those companies' AWPs." (*Id.* at 3.) And it even describes the core elements of the fraud alleged by the Government, including that:

- Medicare and state Medicaid programs "generally use AWP as a benchmark for reimbursement" (*Id.* at 3);
- AWPs "originate with the manufacturer" and "for generic drugs, nearly every manufacturer's price was 60-85% below the published [AWP]" (*Id.* at 2-3);
- "[D]rug salespeople . . . let[] the doctor know that his product has a bigger spread between AWP and the real price than any other generic firm." (*Id.* at 3);
- "If manufacturers deliberately maintain lofty AWPs on their generic drugs . . . the drug makers might then gain market share and higher sales from their customers' over-utilization" (*Id.*); and
- "Some of these AWP's actually have risen, while real wholesale prices have plummeted" (*Id.* at 5).

In short, the allegations put forward in the 1996 *Barron's* article are not only "similar to," but are essentially the same as, the claims made in the Government's First Amended Complaint. Indeed, viewed through the lens of *Springfield Terminal*, not only did this article identify an alleged spread between Abbott's reported AWP (the "X") and its actual prices (the "Y") for all of the drugs at issue, the article also labeled fraudulent the act of marketing the spread (the "Z"). As such, the complaint is "based upon" this disclosure.

Although the *Barron's* article is itself sufficient to trigger the original source inquiry, "marketing the spread" allegations were also publicly disclosed nine years earlier. On July 5, 1987, the Kentucky-based *Lexington Herald-Leader* published a front-page story entitled "Drug Industry Overcharging Medicaid Prescriptions Cost Taxpayers Millions of Extra Dollars." (Ex. K at 1.) The article's premise was that "Medicaid programs across the country are making millions of dollars in overpayments because of flaws and abuses in the way they buy prescription drugs for the poor." (*Id.*) It described how AWPs "theoretically represent how much it would cost an average pharmacy to buy each drug from a wholesaler or distributor," that AWP is used to calculate reimbursements, and that the figures in *Red Book*, *Blue Book*, and *Medispan* are "in most cases . . . provided to the publications by the drug companies." (*Id.* at 2, 3.) It also described in detail a "sales technique called 'playing the spread,'" noting that a large "spread, or difference, between the [AWP] and the actual price" meant that "a pharmacist buying that drug could make a larger profit."[6] (*Id.* at 4-5.)

As with the 1996 *Barron's* article, the 1987 allegations are "similar to" the claims of the First Amended Complaint, and those claims are thus "based upon" this 1987 public disclosure for purposes of the FCA. And although the 1987 article does not specifically identify Abbott, there can be no doubt that it "would not have been difficult for the government to identify [the defendant] as a potential wrongdoer." *In re Pharm. Indus. AWP Litig.*, 538 F. Supp. 2d at 383 n.10 (D. Mass. 2008). The article discloses that the Government knew about "marketing the spread" and AWP inflation nearly a decade before Ven-A-Care filed its *qui* tam, that the Government had the ability to investigate the "spread," but that ultimately in chose not to act.

[6] The article noted that some "companies actually advertised that they had a better spread" and that "many companies routinely list Average Wholesale Prices and 'your price' in their catalogs to show the spread." (*Id.* at 5.) Finally, the article indicated that the Government was aware of the issue, and that previous attempts to change the system had "met bitter resistance" from pharmacists and other groups, which had forced HCFA to back down from making changes. (*Id.* at 8-9.)

B. Ven-A-Care's Now-Defunct Theory That Bare AWP Inflation is Fraud Also Was Publicly Disclosed.

As discussed above, Ven-A-Care's original 1995 complaint was not based on "marketing the spread," but rather on a theory that "AWP inflation" alone was fraudulent. Ven-A-Care's original allegations should be irrelevant, because the only theory of fraud in the Government's First Amended Complaint relates to "marketing the spread." *See Rockwell*, 549 U.S. at 473-74 (looking only to amended complaint in applying the public disclosure test.) Even assuming that a bare AWP inflation theory of fraud were preserved in the First Amended Complaint, though, that also was publicly disclosed well before Ven-A-Care's original complaint was filed in 1995.

1. The "True" And "False" Set Of Facts Regarding The Alleged Inflation Of Vancomycin's AWP Were Disclosed In 1992.

The claims that Abbott had mega-spreads on vancomycin were specifically disclosed in an October 1992 OIG report entitled "Cost of Dialysis-Related Drugs." (Ex. L.) The report detailed an OIG study requested by HCFA in 1991 to determine the relationship of actual acquisition cost to AWP before deciding to use AWP as the benchmark in Medicare reimbursement for dialysis drugs. (*Id.* at 1.) OIG pulled invoices and AWPs for drugs used in end stage renal disease clinics, including vancomycin, and compared these prices to AWP. (*Id.* at 2, 6.) OIG determined that the acquisition cost of 500 mL of vancomycin was $5.00, while the median AWP was $19.17—a "spread" of 283%. (*Id.*) The report specifically noted that vancomycin "is a multiple-source drug" and that OIG "used the median AWP for the generic drug" in its report. (*Id.*) As the study's work papers show, Abbott was then one of only four manufacturers of generic vancomycin, and Abbott's invoice price was used to calculate the median AWP in the OIG report (with that price being above the median.) (Ex. M.)

The OIG's 1992 report thus explicitly identified both the "X" and the "Y" of the claim that vancomycin's AWP was inflated, with respect to a tiny group of generic manufacturers that

OIG knew included Abbott. *In re Pharm. Indus. AWP Litig.*, 538 F. Supp. 2d at 383 n.10; *United States v. Alcan Elec. & Eng'g*, 197 F.3d 1014, 1019 (9th Cir. 1999). Ven-A-Care's 1995 complaint provided essentially identical information, and as such, its 1995 claim of AWP inflation for vancomycin was "based upon" a public disclosure.

2. Allegations Of "AWP Inflation" For Saline, Dextrose, And Sterile Water Intravenous Solutions Were Publicly Disclosed Before 1995.

Allegations of bare AWP inflation for the other three Abbott Subject Drugs (all intravenous solutions) were publicly disclosed long before Ven-A-Care's 1995 complaint. Indeed, public disclosures show that Abbott was discounting these products via GPOs by more than 90% below AWP in the 1980s. Ven-A-Care's officers obtained all of their information as to Abbott pricing from GPO price lists, and Ven-A-Care did nothing more than compare those prices to AWPs. Its allegations are, therefore, based on a public disclosure.

This public disclosure is confirmed by Dr. Bruce Vladeck, who ran both Medicare and Medicaid at the federal level from 1992 to 1997. (Ex. N, at 77:11-81:20.) Dr. Vladeck volunteered that by 1993, he knew, and was not surprised, that there were large spreads on IV products, as he had read *Modern Healthcare* magazine articles in the 1980s disclosing discounts for such products as high as 99% (*i.e.*, a "spread" of up to 10,000%). (*Id.* at 145:9-146:12.) At least one article mentioned Abbott *by name*, reporting in 1980 that Abbott was offering "an 80% discount off current list prices for [IV] solutions."[7] *See* Esther Kuntz, *Hospitals Play Into Hands of Vendors Who Try to Break Group Contracts*, Modern Healthcare, July 1980, at 14-15 (Ex. O).

[7] It is reasonable to assume, based on Dr. Vladeck's testimony, that there were other such disclosures during this time frame; however, there are no electronic records of these materials, and the Government's delay in unsealing this case and preserving potential records of such disclosures have impeded Abbott's ability to mount a defense, as set forth in Abbott's motion for relief from spoliation. Counsel located this 1980 article only after a manual search of a decade's worth of back issues of *Modern Healthcare* at the Library of Congress.

3. Ven-A-Care's 1995 Allegations Were Based On An OIG Investigation.

Ven-A-Care's industry-wide 1995 complaint is further based upon prior industry-wide public disclosures in the form of a parallel OIG invoice study. As reported by *Drug Topics* in 1994, HCFA was "trying to develop an estimate of the difference between the actual acquisition cost of RXs and the AWP" with "data . . . sought from 48 randomly selected chain and independent pharmacies in 12 randomly selected states." Drug Topics, *HCFA Taking Hard Look at Drug Costs*, Nov. 7, 1994 (Ex. P). Among these randomly selected pharmacies was Cobo Pharmacy in Key West, Florida, owned and operated by Ven-A-Care's then-president Luis Cobo. (*See* Ex. E at 31:5-32:1; 103:22-106:4, 390:20-392:14; Ex. Q). As part of that study, OIG agent Paul Chesser and his colleagues extracted invoice prices to develop a comprehensive, statistically valid measure of the percentage difference between AWP and acquisition cost for virtually all products reimbursed by Medicaid. (Ex. R at 156:2-157:10; 464:8-469:16.) Work papers show that in 1994, OIG obtained invoices showing actual prices on all of the Abbott Subject Drugs, along with thousands of other drug products. (*See, e.g.*, Ex. S.) Mr. Chesser noted that IV solutions consistently had invoice prices at a "90 plus percent" discount from AWP. (Ex. R at 626:1-630:7.) Mr. Chesser was also the contact person for the pharmacies selected for the study, and he answered questions they had about the study. (Ex. Q; Ex. R at 616:1-13.) When asked, Mr. Chesser explained to pharmacies the purpose of OIG's study, which was not secret. (Ex. R at 617:7-22.)

Ven-A-Care admits that it knew of the OIG's study in 1994, before filing its complaint. T. Mark Jones testified that he "had several meetings, conversations, with the OIG" about AWP in early 1994, and knew "that the Office of Inspector General, Office of Audit Services, was conducting an investigation in order to determine what the actual prices in the marketplace were for drugs, including those named in the First Amended Complaint." (Ex. C at 415:3-418:18.)

Ven-A-Care's original *qui tam* complaint was filed only three months before the results of OIG's investigation were first announced, and almost a year after the commencement of the OIG study was reported in the Drug Topics article. (*See, e.g.*, Ex. T at 9.) In short, Ven-A-Care and other pharmacies were made aware of an ongoing investigation about alleged AWP inflation before June 1995. This was a public disclosure. *Gross*, 415 F.3d at 603; *Seal 1*, 255 F.3d at 1161.

4. Disclosures Of Industry-Wide "AWP Inflation" Also Set The Government On The Trail Of The Fraud Alleged In The 1995 Complaint.

Finally, widespread allegations of AWP inflation by the industry as a whole, particularly with respect to generic manufacturers,[8] was sufficient to put the Government on the trail of fraud. As the Tenth Circuit recently held, such disclosures are adequate for purposes of the bar. *Natural Gas Royalties*, 562 F.3d 1032. (Ex. I.) In *Natural Gas*, a relator brought suit against over 200 defendants, accusing them of "utilizing several identified mismeasurement techniques to knowingly underreport or cause others to underreport the heating content and volume of gas, with a resultant underpayment of federal royalties." *Id.* at 1037-38. The improper techniques were described in "Senate Committee documents disclos[ing] the mismeasurement of oil and gas on a large scale but did not identify any specific companies" engaged in the practice, as well as

[8] As the Court knows, the issue of AWP inflation was widely disclosed by 1995. Other public disclosures from that time repeatedly addressed AWP inflation, particularly among generic drugs. *See, e.g.*, OIG, Use of Average Wholesale Prices in Reimbursing Pharmacies Participating in Medicaid and the Medicare Prescription Drug Program at 7 (1989) (Ex. U) ("AWP is not a reliable price to be used as a basis for reimbursements for either the Medicaid or Medicare programs."); *see also, e.g.*, Harold Cohen, *There's Nothing 'Average' About AWP*, Drug Store News, June 11, 1990, at 75 (Ex. V) ("AWP has become an exploited figure that is often picked out of thin air by pharmaceutical manufacturers who know that as long as third-party programs continue to use AWP as a base for reimbursement, the higher the number the better their chances are of getting their product dispensed"); *VA Obtains Rx Drug Price Discounts*, The Pink Sheet, July 24, 1989, at 5-7 (Ex. W) ("For multiple-source products . . . the department 'typically' obtains 'discounts ranging from 39% to 93%, but most multiple-source drugs in our depots are currently being purchased with discounts of greater than 80%' off AWP."); Harold Cohen, *AWPs Are a Joke, But No One Is Laughing*, Drug Store News, May 1, 1989, at 195 (Ex. X) ("[t]aking into consideration all the various pricing schedules available from drug manufacturers, the AWP would be a much lower number than is normally used" and that "AWP is being manipulated by many pharmaceutical manufacturers [so that] pharmacists . . . will use or substitute the product with the best AWP"); Barbara Demick, *When Drugstores Tell You No*, Phila. Inquirer, Feb. 12, 1989, at G01 (Ex. Y) ("In a recent study . . . it was found that drugstores actually pay 15 percent less than average wholesale price for brand-name prescription drugs and up to 50 percent less for generics.")

newspaper reports and other disclosures identifying some defendants but indicating the practice was industry-wide. *Id.* at 1039. The Tenth Circuit held that such "public disclosures of . . . mismeasurement by other industry members and in the industry as a whole were sufficient to trigger the public disclosure bar as to Defendants not named in these disclosures," *id.* at 1040, noting that the industry-wide disclosures "provided specific details about the fraudulent scheme and the types of actors involved in it, removing this from a situation where the government would need to comb through myriad transactions performed by various types of entities in search of potential fraud." *Id.* at 1042. Instead, the disclosures allowed the Government to "target its investigation toward specific actors and a specific type of fraudulent activity." *Id.*[9]

This case has remarkable parallels to *Natural Gas*. *First*, just as in *Natural Gas*, the public disclosure of alleged AWP inflation involved allegations of a specific technique, practiced industry-wide, that allegedly caused the Government to make incorrect payments. *See id.* at 1037-38. *Second*, the number of potential AWP wrongdoers are comparable in number, and as easily identifiable, as the 220 named defendants in *Natural Gas*. For drug products to be eligible for Medicaid reimbursement, manufacturers must sign a drug rebate agreement with HCFA. *See* 56 Fed. Reg. 7049 (Feb. 21, 1991). In 1995, only around 450 such manufacturers were eligible. (Ex. Z.) Moreover, generic manufacturers also needed Government approval to sell their products. The number of potential defendants is reduced to 214 when the Medicaid-eligible manufacturers are cross-referenced against generic manufacturers in 1995. *See* U.S. Department of Health & Human Services, *Approved Drug Products with Therapeutic Equivalence Evaluations* at App'x B (15th ed. 1995) (the "Orange Book"). (Ex. AA.)

Third, as in *Natural Gas*, the Government could investigate the alleged fraud, because

[9] The court added that the "government's ability to investigate the potential fraud in this case [was] also furthered" because the Government knew, and had contracts, with the parties paying royalties, had records related to the transactions, and could investigate the defendants based on their relationship. *Id.*

CMS had in its possession actual market prices due to a contractual relationship with the defendants. For its drugs to be Medicaid-reimbursable, Abbott was required to provide the Government with its quarterly "average manufacturer's price," (Ex. AB), understood to be the average price paid by wholesalers, including rebates, discounts, and so on. *See* 42 U.S.C. § 1396r–8(k)(1)(A); Ex. AC at 73:13-74:6.) This figure was understood to be much lower than AWP for generic drugs. (Ex. N, at 462:1-466:12.) Moreover, even apart from the contractual relationship, the Government had ample power to investigate the true prices and to identify wrongdoers once alerted to alleged industry-wide AWP fraud by the public disclosures. *See, e.g.*, 5 U.S.C. app. 3, §§ 1, 4, 6(a)(4), 11 (HHS-OIG may "require by subpena [sic] the production of all information [and] documents . . . necessary" to investigate Medicare and Medicaid fraud).

As in *Natural Gas*, the Government thus had sufficient information from the public disclosures to be "set on the trail of" alleged AWP inflation by Abbott, as is apparent from the fact that the Government *did* investigate Abbott's drug pricing in 1992 and 1994. Thus, even if a bare "AWP inflation" theory was still at issue in this case, this Court would not have jurisdiction to hear it because of the industry-wide public disclosures made prior to 1995.

CONCLUSION

Because the allegations of the 2007 First Amended Complaint were publicly disclosed, and because Ven-A-Care is not an original source of those allegations, the Court lacks subject-matter jurisdiction over the *qui tam* claims first filed by Ven-A-Care in 1995 and 1997. Accordingly, like the relator in *Rockwell*, Ven-A-Care must be dismissed with prejudice from this case.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Brian J. Murray, an attorney, hereby certify that I caused a true and correct copy of the foregoing ABBOTT LABORATORIES INC.'S MEMORANDUM IN SUPPORT OF MOTION TO DISMISS FOR LACK OF SUBJECT-MATTER JURISDICTION UNDER THE PUBLIC DISCLOSURE BAR to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 26th day of June, 2009.

/s/ Brian J. Murray
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